

May 17, 2004

MAY 2 4 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Pkwy. College Park, MD 20740

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Leiner Health Products notifies the FDA that it has begun using the following phrase and statement:

Supports Urinary Tract Health

For years health experts have recommended cranberry to help promote urinary tract health.

CranMax[™] is patented and requires only one dose per day. A proprietary process intensifies the natural benefits of the whole cranberry without any solvents, preservatives, sugars, water, flavoring or color. CranMax[™] has 3 times greater antioxidant activity than cranberry juice and helps support urinary tract health.

on the following product:

YourLife® CranMax™

Very truly yours,

Leiner Health Products

William Cochran, Manager of Regulatory Affairs

975 0162 LET 14266



Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), Center for Food Safety and Applied Nutrition Food and Drug Administration (continued)

The following brands also use the above statement:

Albertson's BI-MART

BIO BALANCE® COUNCIL LABS®

CVS®

ECKERD®

equate®

Hannaford®

HealthLine

health PRIDE

Kash n' Karry

KIRKLAND Signature™

Kroger®

Longs

MARC'S

Member's Mark

MEIJER™

Nature's Origin®

NATURE'S VALLEY™

NATURITE®

NUTRA CHOICE

NUTRI-BLEND

Osco®

PHARMACIST FORMULA®

BODYCOLOGY™

SAFEWAY SELECT™

Sav•on™

Shaw's

ShopKo®

Spring Valley®

TARGET®

TOP CARE®

TRUNATURE®

Wegmans®